

PATENT COOPERATION TREATY



Translation

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2002/006 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/012117	International filing date (day/month/year) 31 October 2003 (31.10.2003)	Priority date (day/month/year) 13 November 2002 (13.11.2002)
International Patent Classification (IPC) or national classification and IPC A61L 15/58		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 10 March 2004 (10.03.2004)	Date of completion of this report 16 February 2005 (16.02.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/012117

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1-14, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-18, filed with the letter of 07 December 2004 (07.12.2004)
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/12117

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

The new set of claims submitted with the letter of 2 December 2004 meets the requirements of PCT Article 19(2) because the content of claims 1-18 does not go beyond the disclosure in the international application as filed.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-5, 7-8, 11-12	YES
	Claims	1-3, 6, 9-10, 13-18	NO
Inventive step (IS)	Claims		YES
	Claims	4-5, 7-8, 11-12	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations

The numbering of the documents is the same as in the search report.

1 Novelty

The content of claims 1-3, 6, 9-10 and 13-18 is not novel within the meaning of PCT Article 33(2).

Document D2 already describes a hot-melt extruded film for the transdermal or mucosal administration of active substances, whose adhesive force develops after humidification (see column 5, lines 3-15). A film for the treatment of wounds contains, *inter alia*, hydroxypropyl cellulose, polyvinyl pyrrolidone, carbomer and polycarbophil, and can be connected to an overlaying adhesive patch (see example 4). A vitamin E adhesive patch against wrinkles and senile lentigo contains, *inter alia*, Gantrez MS-955, polycarbophil and hydroxypropyl cellulose (see example 7). The bioadhesive film also contains organic acids such as tartaric acid (see claim 1 and example 7).

Consequently, the subject matter of claims 1-3, 6, 9-10 and 13-18 is not novel.

2 Inventive step

The subject matter of claims 4-5, 7-8 and 11-12 does not involve an inventive step within the meaning of PCT Article 33(3).

The problem to be solved by the application is that of providing an adhesive for medical adhesive patches, which has improved adhesive properties on a moist substrate.

The solution describes the combination of a copolymer of methylvinyl ether and maleic acid anhydride (PVM/MA copolymer, Gantrez AN) with polyvinyl alcohol, a film-forming polyacrylate such as Eudragit NE 40 D or a pressure sensitive polyacrylate adhesive such as Duro-Tak. Instead of Gantrez AN the acid form of the anhydride can also be used (Gantrez S).

Document D3 is the closest prior art. Claim 3 of document D3 lists a number of polymers which can be used alone or in combination to produce moisture-activated adhesive layers. This list also comprises, *inter alia*, PVM/MA copolymers and polyvinyl alcohols. The examples show that combinations of, for example, Gantrez S-97 with polyvinyl pyrrolidone (example 6) or polyvinyl alcohol with polyvinyl pyrrolidone (example 1) have the desired adhesive force on a moist substrate. A person skilled in the art would therefore be motivated to combine polymers specified in the list for the production of an

adhesive layer because he can expect this to be successful. Consequently, the content of claim 8 cannot be considered inventive because it was not found to have a surprising effect. An analogous argument applies to the subject matter of claim 12. Claim 30 of document D2 lists adhesive polymers used in moisture-activated adhesive layers. These include, *inter alia*, PVM/MA copolymers and acrylic polymers.

For the Examining Authority to be able to recognize an inventive step, the applicant is kindly requested to submit data which show that the present formulation has improved properties with respect to the prior art.

3 Industrial applicability

The subject matter of claims 1-18 is industrially applicable within the meaning of PCT Article 33(4).